



11/Declaration

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re Application of

Karl Kolter et al.

Serial No.09/873,431

Filed: June 5, 2001

For: A process for producing solid oral dosage forms with
sustained release of active ingredient

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DECLARATION

I, Karl Kolter, Dr. rer. Nat., a citizen of Germany and a resident of Sudetenstrasse 1,67117 Limburgerhof, Germany, hereby declare and say as follows:

I am a fully trained pharmacist, having studied pharmacy at Mainz University in the period of from 1976 to 1981.

I was awarded my PhD in Mainz, where in the period of from 1981 to 1985 I worked as an assistant at Mainz University.

I joined Knoll AG, a former subsidiary of BASF Aktiengesellschaft, located in 67061 Ludwigshafen, in 1986, where I have been engaged in research and development in the field of pharmaceutical formulations.

In 1993 I joined BASF Aktiengesellschaft and I have since been engaged in the field of development of pharmaceutical excipients and formulations of active ingredients.

I am a co-inventor to Application Serial No.09/873,431;

I have carefully studied the Office Action of January 27, 2003 and the rejection of the claims under 35 U.S.C. §§ 112 and 103.

Now, hereby, I want to state the following:

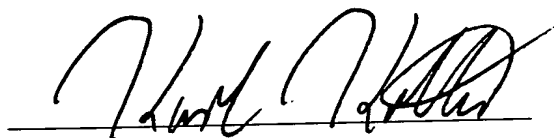
A mixture of polyvinyl acetate and polyvinylpyrrolidone, where the polyvinylpyrrolidone is of a molecular weight higher than 20.000, does not melt completely between 40 and 130°C because the glass transition temperature of such a polyvinylpyrrolidone is higher than 130°C.

By contrast to our invention, Goertz, US 4,801,460 discloses the use of a copolymer of vinylpyrrolidone and vinylacetate, which has a much lower glass transition temperature, e.g. vinylpyrrolidone/vinylacetate 6 :4, which is completely molten under the chosen conditions of the extrusion process.

The attachment shows the glass transition temperature of polyvinylpyrrolidone as a function of the molecular weight and it clearly reveals, that a polyvinylpyrrolidone of a molecular weight of 20.000 has a glass transition temperature of 150°C, which definitely exceeds the maximal processing temperature of our invention of 130°C. To compile this figure values of Kollidon 12 PF (mw: 3,900), Kollidon 17 PF (mw:9,300), Kollidon 25 (mw: 25,700) and Kollidon 30 (mw: 42,500) have been used.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so are made punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed at 67056 Ludwigshafen, Germany, this 16th day of May 2003.

A handwritten signature in black ink, appearing to be 'H. M. Kollidon', written over a horizontal line.

Signature of Declarant



Glass Transition Temperature of Polyvinylpyrrolidone as a Function of Molecular Weight

